REMARKS

A check for $210 for the fee for a two-month extension of time accompanies this response. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Applicant respectfully submits that Preliminary Amendments submitted on April 29, 2004, and on May 11, 2004, do not appear to have been entered. In a Response to Notice of Non-Compliant Amendment, mailed June 3, 2004, the amendments as submitted in the previous preliminary amendments were resubmitted. In the preliminary amendments, claims 1 and 2 were cancelled and claim 3 was amended to more distinctly claim the subject matter. Claim 8 was amended to correct a typographical error. Claims 23-30, 38, 39, 42, 44, 47 and 49-55 were amended to correct dependency. The listing of claims and amendments herein reflect the amendments made in the preliminary amendments.

The specification is amended herein to correct an inadvertent error in the structure of the compound on page 35, line 2 and in Claim 15. The amendment corrects the structure to show the second substituent on the "b" ring to be an ethyl group instead of a methyl group as currently shown. Basis for the amendment is found throughout the specification (for example, see Scheme 1 on page 40 and Scheme 2 on page 42, where all of the compounds have an ethyl group as the second substituent on the "b" ring). No new matter is added.

Claims 3-28, 30-43, 50-61, 63-76, 82-94, 96-109 and 117-124 are pending in this application. Claims 29, 62 and 95 are cancelled without prejudice or disclaimer. Claims 44-49, 77-81 and 110-115 are cancelled herein as directed to non-elected subject matter. Applicant reserves the right to file divisional applications to the cancelled subject matter. It is respectfully submitted that the requirement for restriction is improper and, as discussed below, Groups 1, 2, 8 and 9 and Groups 3, 7 and 10 should be rejoined.

TRAVERSAL OF RESTRICTION REQUIREMENT

Original pending claims 1-124 are subject to a Restriction Requirement. The Office Action sets forth eleven (11) groups for election. Applicant respectfully traverses the restriction requirement.

SUMMARY

Applicant respectfully submits that the Restriction Requirement as currently drafted contains errors. For example, applicant respectfully submits that groups related as combination/subcombination are improperly restricted, as described in detail below. In addition, if the restriction requirement is maintained, applicant respectfully submits that the applicant ultimately could be granted multiple patents that expire on different dates, each of which would include claims to overlapping subject matter, where the later issuing patents could not be held to constitute obviousness-type double patenting. Finally, linking claims have been improperly restricted from claims directed to a species of a genus claimed by the linking claims.

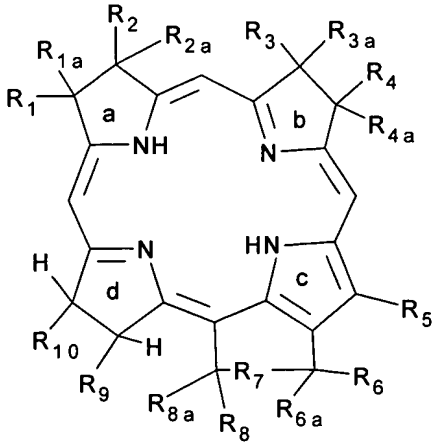
COMBINATION/SUBCOMBINATION

Applicant respectfully submits that as presented, the requirement for restriction as between Group 1 and each of Groups 2, 8 and 9 is not proper. Claims in Group 1 and each of those groups are related as subcombination/combination for which two-way distinctness must be shown in order for restriction to be proper. Restriction may be proper only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. In this instance, the combination of Group 1 and each of Groups 2, 8 and 9 can require the particulars of the subcombination (the compounds of Group 1) for patentability.

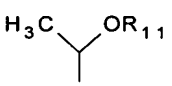
Groups 1 and 2

Claims in Groups 1 and 2 are related as subcombination/combination. Group 1 includes claims directed to tetrapyrrole compounds. For example, claim 3 recites:

Claim 3. A compound of the formula:



or a pharmaceutically acceptable derivative thereof, wherein:

> R_1, R_{1a}, R_2, R_{2a}, R_3, R_{3a}, R_4, R_{4a}, R_5, R_6, R_{6a}, R_8, R_{8a}, R_9, and R_{10} are independently hydrogen, lower alkyl of about 1 through 8 carbon atoms, lower alkenyl of about 1 through 8 carbon atoms, or lower alkyl of about 1 through 8 carbon atoms substituted with at least one halogen, hydroxy, carboxy, ester, aromatic, heterocyclic, ether, amide, or amine group; where two R_1, R_{1a}, R_2, R_{2a}, R_4, R_{4a}, R_6, R_{6a}, R_8, R_{8a} R_9 and R_{10} groups on adjacent carbon atoms may be taken together to form a covalent bond or two R_1, R_{1a}, R_2, R_{2a}, R_3, R_{3a}, R_4, R_{4a}, R_6, R_{6a}, R_8, and R_{8a} groups on the same carbon atom may form a double bond to a divalent pendant group; R_1 or R_2 may additionally be $-CH=CH_2$, -CHO, -COOH, $-COOR_a$, or  ;
>
> R_7 is $-CH_2-$, or $-N(R_{12})-$ or a covalent bond, where
>
> R_{11} and R_{12} are independently hydrogen, lower alkyl of about 1 through 8 carbon atoms, lower alkenyl of about 1 through 8 carbon atoms, or lower alkyl of about 1 through 8 carbon atoms substituted with at least one halogen, hydroxy, carboxy, ester, aromatic, heterocyclic, ether, amide, or amine group;
>
> provided that at least one of R_1, R_{1a}, R_2, R_{2a} R_3, R_{3a}, R_4, R_{4a}, R_5, R_5, R_6, R_{6a} R_7, R_8, R_{8a}, R_9 and R_{10} contains at least one fluorinated pendant group selected from the group consisting of fluorinated alkyl groups, fluorinated phenyl groups and fluorinated heterocyclic moieties.

Group 2 is directed to an article of manufacture that includes a compound of Group 1. For example, claim 57 recites:

> Claim 57. An article of manufacture, comprising packaging material and a compound of claim 3 or a pharmaceutically acceptable derivative of a compound of claim 3 contained within the packaging material, wherein the compound or salt thereof is effective in a photodynamic therapy treatment for ameliorating the symptoms of a hyperproliferative disorder; and the packaging material includes a label that indicates that the compound or salt thereof is used in a photodynamic therapy treatment for ameliorating the symptoms of a hyperproliferative disorder.

Thus, Group 1 and Group 2 are related as a combination (articles of manufacture including the compounds of claims 3, 5 or 6, restricted to Group 2) and a subcombination (the compounds of claims 3, 5 or 6, restricted to Group 1). Inventions that are related as a combination and subcombination are distinct and restriction may be proper only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability and that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

As between subject matter related as combination/subcombination, two-way distinctness is required, which applicant respectfully urges is absent in this instance. In this case, the combination (the articles of manufacture of Group 2) requires the particulars of the subcombination (the compounds of Group 1) for patentability. Therefore, as between Group I and Group 2, restriction is not proper. Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between Group 1 and Group 2 is respectfully requested.

Group 1 and 8

Claims in Groups 1 and 8 are related as subcombination/combination. As discussed above, Group 1 includes claims directed to tetrapyrrole compounds and pharmaceutical compositions that includes the compounds. Group 8 includes claims directed to kits to treat hyperproliferative disorders, where the kits include the compounds restricted to Group 1. For example, claim 85 recites:

> Claim 85. A kit to treat hyperproliferative disorders, comprising the compound of claim 3 or a pharmaceutically acceptable derivative thereof and instructions teaching a method of photodynamic therapy.

Thus, Group 1 and Group 8 are related as a combination (kits including the compounds of claims 3, 5 or 6, restricted to Group 1) and a subcombination (the compounds of claims 3, 5 or 6, restricted to Group 1). Inventions that are related as a combination and subcombination are distinct and restriction may be proper only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability and that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

As between subject matter related as combination/subcombination, two-way distinctness is required, which applicant respectfully urges is absent in this instance. In this case, the combination (the kits of Group 8) requires the particulars of the subcombination (the compounds of Group 1) for patentability. Therefore, as between Group 1 and Group 8, restriction is not proper. Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between Group 1 and Group 8 is respectfully requested.

Group 1 and 9

Claims in Groups 1 and 9 are related as subcombination/combination. As discussed above, Group 1 includes claims directed to tetrapyrrole compounds and

pharmaceutical compositions that includes the compounds. Group 9 includes claims directed to a combination that includes the compounds of claims 3, 5 or 6 of Group 1 and a light source or a magnetic resonance imaging device. For example, claims 87 and 88 recite:

> Claim 87. A combination, comprising:
> the compound of claim 3 or a pharmaceutically acceptable derivative thereof; and a light source.
>
> Claim 88. A combination, comprising:
> the compound of claim 3 or pharmaceutically acceptable derivatives thereof; and a magnetic resonance imaging device.

Thus, Group 1 and Group 9 are related as a combination (combinations including the compounds of claims 3, 5 or 6, restricted to Group 1) and a subcombination (the compounds of claims 3, 5 or 6, restricted to Group 1). Inventions that are related as a combination and subcombination are distinct and restriction may be proper only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability and that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

As between subject matter related as combination/subcombination, two-way distinctness is required, which applicant respectfully urges is absent in this instance. In this case, the combination (the combinations of Group 9) requires the particulars of the subcombination (the compounds of Group 1) for patentability. Therefore, as between Group 1 and Group 9, restriction is not proper. Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between Group 1 and Group 9 is respectfully requested.

Hence, applicant respectively requests that Groups 1, 2, 8 and 9 be rejoined.

Multiple Patents

Also, it is apparent that this requirement is improper, if one considers the outcome if patents issue based upon these four groups. If the claims are restricted into these four groups, applicant ultimately could be granted four patents that expire on different days and/or are not required to be commonly owned. Obviousness-type double patenting cannot be held. See MPEP 806, paragraph 3, which states:

> [w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the

> Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

> 35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

In this instance, if the restriction requirement as between groups 1, 2, 8 and 9 is maintained, the Office is precluded from rejecting the claims for obviousness-type double patenting. Therefore, reconsideration of the requirement for restriction as between and among these groups is respectfully requested.

Group 3 and 7 or Group 3 and 10

Although the claims in groups 3, 7 and 10 are not elected herein, arguments for rejoinder are presented because a divisional application with the claims in these groups may be filed. Claims 30, 63 and 96 and claims dependent thereon (restricted to Group 3) are linking claims (genus claims) that must be examined with either Group 7 or Group 10.

Group 3 and 7

Applicant respectfully submits that claims restricted to Group 3 are related to claims restricted to Group 7 as genus/species. Claims restricted to Group 3 are directed to methods for administering a therapy to produce a therapeutic effect, the method including administering a compound of claims 3, 5 or 6. For example, claims 30, 63 and 96 recite:

Claim 30. A method for administering a therapy to a target, comprising:
(i) administering to a subject the compound of claim 6 or a pharmaceutically acceptable derivative thereof that preferentially associates with the target, and
(ii) irradiating the subject with light of a wavelength and total fluence sufficient to produce a therapeutic effect.

Claim 63. A method for administering a therapy to a target, comprising:
(i) administering to a subject the compound of claim 3 or a pharmaceutically acceptable derivative thereof that preferentially associates with the target, and
(ii) irradiating the subject with light of a wavelength and total fluence sufficient to produce a therapeutic effect.

Claim 96. A method for administering a therapy to a target, comprising:
(i) administering to a subject the compound of claim 5 or a pharmaceutically acceptable derivative thereof that preferentially associates with the target, and
(ii) irradiating the subject with light of a wavelength and total fluence sufficient to produce a therapeutic effect.

Hence, these claims are directed to methods for administering a therapy that includes administering to a subject a compound of claim 3, 5 or 6 or a pharmaceutically acceptable derivative thereof and irradiating the subject with light of a wavelength and total fluence sufficient to produce a therapeutic effect.

Claims restricted to Group 7 are directed to methods of administering a therapy that includes administering to a subject a compound of claim 3, 5 or 6 or a pharmaceutically acceptable derivative thereof and irradiating the subject with light of a wavelength and total fluence sufficient to produce a therapeutic effect, where the therapeutic effect is the destruction or impairment of hyperproliferative tissue. For example, claims 50, 83 and 116 recite:

Claim 50. A method of providing a medical therapy to an animal, comprising:
(i) administering to the animal the compound of claim 6 or a pharmaceutically acceptable derivative thereof, and
(ii) irradiating the animal with light of a wavelength and fluence sufficient to activate the compound, whereby the hyperproliferative tissue is destroyed or impaired.

Claim 83. A method of providing a medical therapy to an animal, comprising:
(i) administering to the animal the compound of claim 3 or a pharmaceutically acceptable derivative thereof, and
(ii) irradiating the animal with light of a wavelength and fluence sufficient to activate the compound, whereby the hyperproliferative tissue is destroyed or impaired.

Claim 116. A method of providing a medical therapy to an animal, comprising:

(i) administering to the animal the compound of claim 5 or a pharmaceutically acceptable derivative thereof, and

(ii) irradiating the animal with light of a wavelength and fluence sufficient to activate the compound, whereby the hyperproliferative tissue is destroyed or impaired.

Hence, claims 50, 83, and 116 and claims dependent thereon, restricted to Group 7, are a species (methods of providing a therapy to produce a therapeutic effect, where the therapeutic effect is the destruction or impairment of hyperproliferative tissue) of the genus restricted to Group 3 (methods of providing a therapy to produce a therapeutic effect).

Group 3 and 10

Applicant respectfully submits that claims restricted to Group 3 are related to claims restricted to Group 10 as genus/species. Claims restricted to Group 10 are directed to methods of providing a therapy to produce a therapeutic effect, where the therapeutic effect is the destruction or impairment of hyperproliferative tissue, the method including administering a compound of claim 3, 5 or 6 or a pharmaceutically acceptable derivative thereof that preferentially associates with a hyperproliferative tissue. For example, claims 71 and 104 recite:

Claim 71. A method of photodynamic therapy for treating hyperproliferative tissue in a subject, comprising:

(i) administering to the subject the compound of claim 3 or a pharmaceutically acceptable derivative thereof that preferentially associates with the hyperproliferative tissue, and

(ii) irradiating the subject with light of a wavelength and fluence sufficient to activate the compound, whereby the hyperproliferative tissue is destroyed or impaired.

Claim 104. A method of photodynamic therapy for treating hyperproliferative tissue in a subject, comprising:

(i) administering to the subject the compound of claim 5 or a pharmaceutically acceptable derivative thereof that preferentially associates with the hyperproliferative tissue, and

(ii) irradiating the subject with light of a wavelength and fluence sufficient to activate the compound, whereby the hyperproliferative tissue is destroyed or impaired.

Hence, claims 71 and 104 and claims dependent thereon, restricted to Group 10, are a species (methods of providing a therapy to produce a therapeutic effect, where the

therapeutic effect is the destruction or impairment of hyperproliferative tissue) of the genus restricted to Group 3 (methods of providing a therapy to produce a therapeutic effect). Therefore, the claims currently restricted to Group 7 and to Group 10 are a species of the genus linked by claims 30, 63 or 96 of Group 3. Thus, Group 3 claims are related to Group 7 and Group 10 claims as genus/species.

A genus must always be examined with a species within its scope. Hence Group 3 includes genus claims, which are linking claims (see MPEP §809.03, which defines one type of linking claim as a genus claim linking species claims). Pursuant to MPEP §809, when claims linking more than one group are found, the Restriction Requirement must be conditioned on:

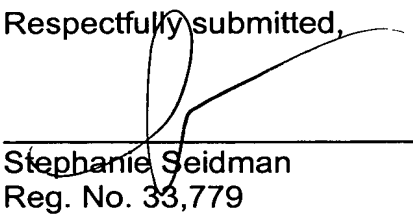
1) specifying the linking claims; and
2) examining the linking claims with the elected group.

The linking claims must be examined with the elected group; if the linking claims are deemed allowable, then the restriction requirement must be withdrawn and all claims directed to nonelected subject matter which depends from or includes all the limitations of the linking claims must be rejoined. In this case, Group 3 includes claims linking it to Group 7 and Group 10. Accordingly, restriction among these groups is improper.

* * *

In view of the provisional election, amendments and remarks herein, examination on the merits is respectfully requested.

Respectfully submitted,



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